Masten.Scott

From: TheWrenGrp@aol.com
Sent: Tuesday, August 7, 2001 11:39 AM
To: masten@niehs.nih.gov
Subject: Grape seed extract

Dear Scott,
Following your request to be kept up to date with progress in the area of "nutraceuticals" and as a thank you for our useful discussions earlier this year, I'm pleased to report that we have submitted a paper on the successful 90-day feeding study in rats of a proanthocyanidin-containing grape seed extract to Agric., Food Chem. This is a prelude to seeking FDA approval of our self determination of GRAS status.
I would also like to report that Dry Creek Nutrition Inc, a subsidiary of EJ Gallo, (and my client) were awarded FEMA GRAS for this extract in June after submitting data including the feeding study reports. The study was carried out by SRI to full GLP and with the highest dose of the extract as 2%w/w of the diet.
I'll forward a copy of the paper as soon as I hear that it has been accepted for publication.
On a slightly different matter, it was recently published in the Federal Register that GSE and epigallocatechin gallate have been nominated for tox studies and testing by NTP. I remember your telling me that nomination is very different form being chosen and that if it IS chosen, the studies will be conducted several years from now. I would be most grateful if you could let me know the NTP thinking behind thid request, especially in light of the fact that we have conducted a dull toxicity study with no ill effects whatsoever. In addition, Polyphenolics, the producer of both a grape seed extract and grape extract claimed, at IFT this year, to have completed successful feeding studies and mutagenicity testing of both and that they were seeking FDA GRAS in the very near future.
What are your thoughts regarding the testing nomination for GSE?
Thanks,
ALLISON